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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,720	04/24/2001	Lei Yu	INDA:002USD1/10103856	6286

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,720

Applicant(s)

YU, LEI

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24,26-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. Claims 19-24, 26-32 and 34-37 were pending in this application. In the Amendment dated 1/23/04, Applicants added new claim 38. Therefore, claims 19-24, 26-32 and 34-38 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Title

- A. The objection to the specification has been withdrawn in view of Applicants' amendment to the title to more clearly reflect the claimed subject matter.

3. Figures

- A. The objection to Figure 1 has been withdrawn in view of Applicants' amendment to the specification to refer to Figures 1A and 1B.

4. Claim Objections

- A. Claim 24 remains objected to for the reasons already of record on page 2 of the Office Action dated 10/20/03. Applicants state that claim 24 has been amended to recite "wherein the nucleic acid sequence encodes SEQ ID NO:2." However, this amendment was not made.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claims 19-22, 26-31, 34, 36 and 37 remain rejected and new claim 38 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 10/20/03. Applicants argue that there is no need for a functional receptor and that there is utility for receptors other than ones which function, such as for the production of antibodies.

These arguments have been considered, but are not deemed persuasive. The claims recite a process for screening a candidate substance for its ability to bind to an opioid receptor. Intended in the previous rejection was that the function of the receptor encompassed ligand binding to the receptor. Applicants are claiming a screening process in which a receptor fragment as few as 25 contiguous nucleotides of SEQ ID NO:1 (8 amino acids of a 398 amino acid protein) is used. Applicants have not

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provided any guidance or working examples of which regions of the protein of SEQ ID NO:2 are able to bind a candidate substance, which include non-antibody ligands. Furthermore, it is not predictable to one of ordinary skill in the art which amino acids are critical for ligand binding to the receptor, nor is it predictable that a ligand which binds to a small fragment of SEQ ID NO:2 would, in fact, bind the full-length opioid receptor. As written, the breadth of the claims is excessive with regard to Applicants claiming a process for screening any and all candidate substances for their ability to bind to an opioid receptor, given that as few as 8 amino acids are required, or for all opioid receptors which comprise at least 25 contiguous bases of SEQ ID NO:1. If Applicants intend for the claims to encompass only antibodies, as appears from their arguments, then the claims should be limited to a process for screening for antibodies which bind SEQ ID NO:2.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 19-22, 26-31, 34, 36 and 37 remain rejected and new claim 38 is also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 10/20/03. Applicants argue that there are structural limitations in the claims – that the receptor must comprise at least 25 contiguous bases of SEQ ID NO:1 and that thousands of species meet this limitation. Applicants further argue that a common function of all of these species is the binding of antibody. Applicants further argue that they do not need to disclose each and every embodiment on which the claims read and that there are numerous patents which recite or claim polynucleotide and polypeptides with limited sequence identity to a referenced sequence.

These arguments have been considered, but are not deemed persuasive. First, all issued U.S. Patents are presumed valid. Second, the specification provides a written description of only one nucleic acid constructs (SEQ ID NO:1) which encodes one full-length opioid receptor (SEQ ID NO:2). The only structural limitation in the claim is that the receptor must comprise at least 25 contiguous bases of SEQ ID NO:1. No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of opioid receptor proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding these opioid receptors, or nucleic acids encoding opioid receptors from any different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph. If, as Applicants argue, a common function of all of these species is the binding of antibody, then if Applicants intend for the claims to encompass only antibodies, then the claims should be

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limited to a process for screening for antibodies which bind SEQ ID NO:2. As stands, neither the specification nor claims adequately describe which nucleotide or amino acid residues are critical to maintain the non-antibody ligand binding characteristics of the opioid receptor of SEQ ID NO:2.

7. Claim Rejections - 35 USC § 112, second paragraph

A. Claims 26 and 36 remain rejected for the reasons already of record on page 5 of the Office Action dated 10/20/03. The rejection of parts (i) and (ii) are withdrawn in view of Applicants' amendments to the claims. However, parts (iii) and (iv) remain rejected. Applicants argue that a person of ordinary skill in the art would recognize that one way to evaluate whether a candidate substance bound to a recombinant opioid receptor polypeptide is to measure a downstream event, such as activation of ion channels in a cell membrane or modulation of ion channels in the cell membrane. However, the claims do not provide a nexus between ion channel activation and the binding of a substance to a receptor. In other words, it is not clear that the ion channel affected by the substance is a downstream effector of the claims opioid receptor.

B. The rejection of claims 28-32 and 34 under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' arguments that there is a difference in the claims regarding "expressing" a protein vs. "providing" a protein.

C. All rejections of claims 35-37 on page 6 of the Office Action dated 10/20/03 under 35 USC 112, second paragraph, have been withdrawn in view of Applicants amendments to the claims to remove the recitation of "agonist or antagonist."

8. Double Patenting

A. Claims 19-24, 26-32 and 34-36 remain provisionally rejected and new claim 38 is also rejected under 35 U.S.C. 101 as claiming the same invention as that of one or more claims of copending Application No. 09/626,616. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Applicants argue that they will address this rejection if the present claims become allowable.

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9. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' arguments. The Examiner apologizes for inadvertently reciting both "Evans" and "Chen" in the same rejection. Applicants are correct in that the first reference was drawn to Chen. The Examiner appreciates Applicants' correction.

10. Claim Rejections - 35 USC § 103

A. The rejection of claims 27 and 34 under 35 USC 103 as being unpatentable over Chen in view of Xie has been withdrawn for the reasons seen in the above rejection under 35 USC 102.

B. Claims 27 and 34 remain rejected under 35 USC 103 as being unpatentable over Evans in view of Xie. Furthermore, claims 19-21, 26 and 28-30 are also rejected. Applicants argued in the rejection under 35 USC 102 that Evans do not teach the clone in the Sequence Comparison attached to the previous Office Action as being used in a screening process. However, regardless of whether or not this clone was used, it is still an opioid receptor clone. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the present invention to use any opioid receptor in a screening process. Regarding the request for application 07/929,200, Applicants are requested to see Section 103 of the M.P.E.P.

11. Conclusion

A. No claim is allowable.

Advisory information

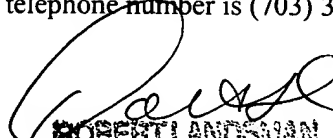
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
February 17, 2004



ROBERT LANDSMAN
PATENT EXAMINER